

REMARKS

Claims 1-60 were pending prior to entry of the present amendment, and Claims 43-60 were under consideration. With this amendment, Claims 1-42, drawn to non-elected subject matter, and Claims 45 and 46 are cancelled without prejudice to Applicants' right to pursue the subject matter of the cancelled claims in related applications, Claims 43, 47, 51, and 58 are amended, and new Claims 61 and 62 are added. Thus, following entry of the present amendment, Claims 43, 44, and 47-62 will be pending and under consideration.

I. The Amendments to the Claims

Claims 43, 47, 51, and 58 have been amended in order to more distinctly claim and particularly point out that which Applicants regard as their invention. In particular, Claims 43, 47, and 51 have been amended to recite that activation of the leptin receptor or formation of the leptin/leptin receptor complex results in decreased bone mass, while Claim 58 is amended to correct a minor grammatical error. Support for the amendments to Claims 43, 47, 51, and 58 may be found throughout the specification and specifically at, for example, page 3, lines 11-17, page 10, lines 23-31, Examples 6.2, 6.3 and 6.4, and Claim 58 as originally filed. Thus, the amendments to Claims 43, 47, 51, and 58 are fully supported by the application as filed and do not introduce new matter.

Further, new Claims 61 and 62 are presented in order to more distinctly claim and particularly point out that which Applicants regard as their invention. New Claims 61 and 62 are directed to methods of identifying a compound to be tested for an ability to increase bone mass by preventing activation of a leptin receptor. Support for new Claims 61 and 62 may be found throughout the application as filed and specifically at, for example, page 3, lines 11-17, page 10, lines 23-31, Examples 6.2, 6.3 and 6.4, and Claims 47, 48, and 59 as filed. Thus, new Claims 61 and 62 are fully supported by the application as filed and do not introduce new matter.

Accordingly, entry of the present amendment to the claims is hereby respectfully requested under 37 C.F.R. § 1.111.

II. Priority

The PTO asserts that the methods recited by Claims 43-60 are not supported in Provisional Application No. 60/138,733 ("the '733 application"). Applicants respectfully submit that one of skill in the art would recognize that Applicants were in possession of the claimed methods based, at least, on the disclosure of the '733 application at page 2, line 21 to page 3, line 19 and Examples 2-5. Here, Applicants describe methods of treating bone

disease by modulating leptin concentrations as well as assays to determine bone mass and leptin concentrations in subjects that have experienced such modulation. Thus, Applicants respectfully submit that the ordinarily-skilled artisan would recognize that Applicants were in possession of the currently claimed methods of identifying compounds that can increase or decrease bone mass by modulating leptin or the leptin receptor at the time the '733 application was filed. Accordingly, Applicants respectfully submit that the present claims are entitled to the priority date of the '733 application, filed June 11, 1999.

III. The Rejection of Claims 43-60 as Obvious under 35 U.S.C. § 103(a)

Claims 43-60 stand rejected as obvious over U.S. Patent No. 6,352,970 by Ke *et al.* ("the '970 patent") in view of U.S. Patent No. 6,403,552 by Tartaglia *et al.* ("the '552 patent"), U.S. Patent No. 5,935,810 by Friedman *et al.* (the '810 patent), and Simonet *et al.*, 1997, *Cell* 89:309-319 ("*Simonet*"). Applicants respectfully traverse the rejection on the grounds that the cited references, even if they could be validly combined, do not teach each and every element of the invention as presently claimed.

A. The Legal Standard

To reject a claim as under 35 U.S.C. § 103(a), the PTO bears the initial burden of showing an invention to be prima facie obvious over the prior art. *See In re Bell*, 26U.S.P.Q.2d 1529 (Fed. Cir. 1992). If the PTO cannot establish a prima facie case of unpatentability, then without more the applicant is entitled to grant of the patent. *See In re Oetiker*, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). The PTO must meet a three-part test to render a claimed invention prima facie obvious.

To begin with, the prior art references cited by the PTO must provide "motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant." *See In re Kotzab*, 55 U.S.P.Q.2d 1316 (Fed. Cir. 2000). Where one reference is relied upon by the PTO, there must be a suggestion or motivation to modify the teachings of that reference. *See id.* Where an obviousness determination rests or relies on the combination of two or more references, there must be some suggestion or motivation to combine the references. *See WMS Gaming Inc. v. International Game Technology*, 51U.S.P.Q.2d 1386 (Fed. Cir. 1999). The suggestion may be found in implicit or explicit teachings within the references themselves, from the ordinary knowledge of one skilled in the art, or from the nature of the problem to be solved. *See id.*

Second, the prior art references cited by the PTO must suggest to one of ordinary skill in the art that the invention would have a reasonable expectation of success. *See In re Dow Chemical*, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988). The expectation of success, like the motivation to combine two prior art references, must come from the prior art, not the applicant's disclosure. *See id.*

Finally, the PTO must show that the prior art references, either alone or in combination, teach or suggest each and every limitation of the rejected claims. *See In re Gartside*, 53 U.S.P.Q.2d 1769 (Fed. Cir. 2000). If any one of these three factors is not met, the PTO has failed to establish a prima facie case of obviousness and the applicant is entitled to grant of a patent without making any affirmative showing of non-obviousness.

B. The Cited References do not Teach or Suggest Each and Every Element of the Claimed Invention.

The PTO argues that the combination of the '970 patent, the '522 patent, the '810 patent, and *Simonet* teach or suggest every element of the claimed invention. In particular, the PTO considers the '970 patent to be the primary reference that teaches leptin as a regulator of bone formation, use of leptin or a leptin mimetic to treat diseases associated with bone mass, and assays to determine bone mass in animals *in vivo*.

However, the '970 patent does not teach or suggest that activation of the leptin receptor mediated by leptin/leptin receptor complex formation results in *decreased* bone mass as recited by all of the currently pending claims. Rather, the '970 patent actually teaches that leptin/leptin receptor complex formation results in a signal transduction cascade that eventually causes *increased* bone mass. Thus, the '970 patent actually teaches away from the methods as presently claimed. None of the other cited references even hint that leptin could modulate bone mass. Thus, the cited references, even if they could be validly combined, do not teach or suggest each and every element of the invention as presently claimed.

Because the cited references do not teach or suggest each and every element of the invention, Claims 43-60 are not obvious over the '970 patent in view of the '522 patent, the '810 patent, and *Simonet*. Accordingly, Applicants respectfully submit that the rejection of Claims 43-60 as obvious under 35 U.S.C. § 103(a) is in error and earnestly request its withdrawal.

CONCLUSION

Applicants respectfully request that the present amendment be entered and the remarks made of record in the instant application. Applicants believe that the present

amendment places the claims in condition for allowance and kindly solicit early indication of the same. If a teleconference would facilitate passage of the claims to issuance, the Examiner is respectfully invited to telephone the undersigned attorney to discuss any remaining issues.

No fee is believed due in connection with this amendment. However, the Commissioner is authorized to charge all required fees, fees under 37 C.F. R. §1.17 and all required extension of time fees, or credit any overpayment, to Pennie & Edmonds LLP U.S. Deposit Account No. 16-1150 (9142-006-999).

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Respectfully submitted,



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